UPPERESOPHAGEAL SPHINCTER PRESSURE VARIATION

DURING ANESTHESIA INDUCTION

Date: January 1st, 2017.

PATIENT INFORMATION SHEET AND INFORMED CONSENT

CLINICAL STUDY ON UPPER ESOPHAGEAL SPHINCTER MOTILITY VARIATION DURING GENERAL ANESTHESIA INDUCTION

Hypnotics employed during general anesthesia induction may cause alterations in upper esophageal sphincter motility: they can decrease its pressure, which may enable aspiration of gastro-esophageal contents into the respiratory tract potentially causing pneumonitis (inflammation) or pneumonia (infection).

Some studies have made conclusions on this subject, not always agreeing.

Our study pretends to determine the isolated effect of hypnotics on upper esophageal sphincter, avoiding interferences in those results with other type of coadministered drugs such as local anesthestics or sedatives, commonly used in previous studies. For our purpose, optimal measurements will be made by using high resolution manometry, not always employed in other studies.

Level of consciousness will be measured using entropy, which analyzes the electroencephalogram, causing no harm to you.

STUDY OBJECTIVES

Find out the effect that commonly used hypnotic doses for general anesthesia induction has on upper esophageal sphincter pressure.

Conclude if there is any association between the level of consciousness (measured with entropy) and upper esophageal sphincter pressure.

Register any possible alterations of hypnotics of blood pressure, heart rate or blood oxygenation.

The final objective is to identify if any of the commonly used hypnotics may preserve upper esophageal sphincter pressure and so keep airway protected during induction of general anesthesia.

ACTION PROTOCOL

It will take place after 6-8 hours fast. Once patient is laying on the stretcher, he/she will be monitored with entropy, ECG (to follow up heart rate and any possible alterations in cardiac rythm), pulsioximetry (to measure blood oxygen), sphyngomanometer (to check blood pressure). A manometry probe will be then introduced through the nostril to be located definetely from the nose to the stomach. After 1 minute for the patient to get used to it, administration of the hypnotic will be done over 30 seconds to reach uncociousness. Once entropy reaches a value of 60 or otherwise clinical effects of the hypnotic are shown, the study will be over and manometry probe will be taken out. General anesthesia procedure will continue as planned.

High resolution manometry is a little invasive procedure commonly done by the gastroenterologist in daily practice and not in a surgery room, not even using local anesthesia in most cases.

Hypnotic used is well known and has been commonly used safely in daily practice over decades.

Duly authorized by ethics comitee of Clinico San Carlos Hospital, the study is taking place in order to find out if there is an alteration in upper esophageal sphincter motility during induction of general anesthesia using propofol, etomidate or thiopental.

To date, previous studies show:

1. Upper esophageal sphincter pressure is not always affected and in the same manner by hypnotics. Published results may be altered by other drugs administered during the studies.
2. Manometry is the instrument indicated to measure upper esophageal sphincter pressure, but high resolution manometry which is the optimal technique, has only been used recently.
3. Given that upper esophageal sphincter has an important role on airway protection against aspiration, an alteration of its function is of vital concern.

The objective of this report is to obtain your consent to participate in this study.

If you agree to participate, you should sign the inform consent sheet which is provided. Your decision to take part of this study depends completely on you and all registered information will be confidential. You physician will respect your confidentiality

assigning to your records a number and a color, never you personal data, avoiding any possible identification in accordance to Organic Data Protection Law.

Should you need more information after the study about itself or about your rights as a patient, you can contact the hospital Anesthesiology Department.

Finally, you have the right to deny your authorization to participate in this study before, during and after having been included in it; not having any consequences for the procedure of your surgery management as planned.

INFORMED CONSENT

Miss/Mister. I recognize being informed, I understand the information, and I have received any needed clarifications to the respect by the anesthesiologist.

I do CONSENT to participate in the study.

DATE

PATIENT the anesthesiologist.

I do NOT CONSENT to participate in the study.

DATE

PATIENT the anesthesiologist.